REMARKS

This is in response to the Final Rejection which was mailed March 26, 2008.

Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54 were finally rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/08229 ('229) by itself or in view of US 5,993,849 ('849).

The '229 disclosure is only very general at best with respect to a transdermal formulation containing fentanyl, and the otherwise general disclosure of the amount of drug that can be present, given the myriad of drugs disclosed in the '229 publication and the lack of any emphasis on fentanyl, underscores the insufficiency of this teaching in respect to the pending claims which are directed to transdermal formulations containing a relatively high concentration of fentanyl. Again it is asserted that the '229 publication does not lead one skilled in the art to a finding that 8-30% fentanyl by weight would fully dissolve in the claimed formulations.

The alleged equivalency of nicotine and fentanyl which the examiner points to in the '849 publication does not remedy this deficiency in the '229 publication. Nicotine and fentanyl are dissimilar in more respects than they are similar, and again it is underscored that nicotine is not even a solid at room temperature. And it is not understood how Naik et al. which compares bioavailability and pharmacokinetics of nicotine and fentanyl teaches anything about a formulation containing an acrylate copolymer and a high loading of dissolved fentanyl.

Finally, Roy et al. is very pertinent to the allowability of the instant claims. This publication speaks directly to fentanyl/acrylate copolymer formulations. Importantly, this publication discloses the fact that formulations containing over 4% fentanyl had undissolved fentanyl particles in addition to dissolved fentanyl. It is very undesirable to have both dissolved and undissolved drug in a transdermal patch. Thus Roy et al. is a clear teaching away from the formulations of the instant invention.

Applicants would like correct a possible misunderstanding by the Examiner relative to Roy et al.. The sole acrylate adhesive disclosed in Roy et al., namely “Gelva 737”, is believed by Applicants to be a copolymer containing 72% 2-ethylhexyl acrylate and 28% vinyl acetate. As such, that copolymer meets the limitations of the copolymer recited in for example Claim 1 of the instant application. Nonetheless, the language at the end of that claim “wherein the composition is free of undissolved fentanyl” serves to exclude any formulation where the

combination of copolymer and the amount of fentanyl are such that there is undissolved fentanyl in the formulation. If anything, the fact the acrylate disclosed in Roy et al. meets the limitations of the copolymer recited in instant Claim 1 further underscores the allowability of that claim.

Reconsideration and withdrawal of the Final Rejection of Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54, and allowance of the same are respectfully requested in view of the above comments.

Respectfully submitted,

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